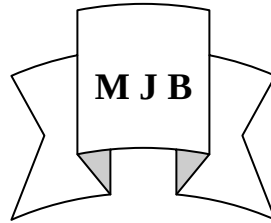


Evaluation of the Side Effect and Complications of Daily Low Dose Aspirin Therapy on Minor Oral Surgery (Clinical and Follow Up Prospective Study)

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Abstract

Background (Aims of the study): The risk of excessive bleeding prompts physicians to stop low-dose long-term aspirin regimens before surgery, which puts the patient at risk from adverse thrombotic events. We hypothesize that most minor oral surgical procedures can be carried out safely without stopping low-dose aspirin.

Materials and Methods: The study included 60 patients (35 males, 25 females), ranging in age from 45 to 75 years. All minor oral surgery patients at (Oral& Maxillofacial Surgery Department in College of Dentistry and AL-YARMOUK hospital) from September 2010 to April 2011, who were also on long-term low-dose aspirin therapy regimens (acetylsalicylic acid 75 mg to 100 mg/day), were included. Investigation of bleeding time and platelet count was performed. If within normal limits, aspirin was not stopped before surgery. Patients were operated under local anesthesia on an outpatient basis. All wounds were sutured and followed up at 24, 48, and 72 hours, 1 week, and 2 weeks after the procedure.

Results: The study included 60 patients (35 males, 25 females), ranging in age from 45 to 75 years. Preoperative values were within normal limits for all patients. Aspirin was not stopped for a single patient. There was no excessive intraoperative bleeding in all cases except 2 cases; there was no postoperative bleeding in all cases.

Conclusion: We conclude that most minor oral surgery procedures can be carried out safely without stopping long-term low-dose aspirin regimen.

تأثير الاسبرين على المرضى بدون توقف الجرعة اليومية المنخفضة منه اثناء وبعد العمليات الجراحية الفموية الصغرى (دراسة سريرية ومتابعة)

الخلاصة

لقد تم اجراء هذه الدراسة سريريا على (٦٠) مريضا تتراوح اعمارهم من (٤٥ سنة الى ٧٥ سنة) ولقد كان عدد الذكور (٣٥) وعدد الاناث (٢٥) يتعاطون الاسبرين يوميا بجرعة تتراوح من (٧٥ ملغم الى ١٠٠ ملغم).

هؤلاء المرضى تم اجراء الدراسة عليهم في قسم جراحة الفم والوجه والفكين في كلية طب الاسنان - جامعة بابل وايضا في مستشفى البرموك التعليمي (من ايلول ٢٠١٠ الى نيسان ٢٠١١).

لقد تم اجراء التحليلات المختبرية المسبقة لكل المرضى قبل اجراء العمليات الجراحية الصغرى في الفم لهم ولقد تضمنت التحليلات (نسبة الصفائح الدموية في الدم ومقدار الوقت اللازم لتوقف النزيف)، ولقد وجدنا ان نتائج التحاليل المختبرية كانت طبيعية لجميع المرضى.

تم اجراء العمليات الجراحية الصغرى في الفم لهؤلاء المرضى وحسب الحالات الواردة الينا باستخدام التخدير الموقعي، وتراوحت الحالات من قلع اعتيادي الى قلع سن العقل جراحيا.

ومن الجدير بالذكر انه تم اجراء جميع العمليات الجراحية الصغرى لجميع المرضى بدون قطع او توقف الجرعة اليومية للاسبرين

ولقد وجدنا انه لم تحدث اي مضاعفات خلال العمليات الا باستثناء حالتين حدث فيها نزيف زائد خلال العمل، ولقد تمت السيطرة عليه من خلال استعمال مادة اسفنجية موقفة للنزيف مع الضغط لمدة ١٠ دقائق، ولقد تضمنت هاتان الحالتان قلعا جراحيا من المحتمل تسبب باصابة احد الاوعية الدموية القريبة.

في هذه الدراسة تم استخدام الخيط الجراحي لجميع الحالات وذلك لمنع حدوث اي نزيف غير متوقع بعد انتهاء العملية، وبالفعل لم تسجل اي حالة نزف بعد العملية، وذلك من خلال المتابعة الدورية لجميع المرضى بعد (٣٠ دقيقة- ٢٤ ساعة- ٤٨ ساعة- ٧٢ ساعة- اسبوع- اسبوعان).

لقد توصلنا من خلال هذه الدراسة انه من الممكن اجراء معظم العمليات الجراحية الصغرى في الفم بدون توقف او قطع الجرعة اليومية المنخفضة للاسبرين.

Introduction

Acetylsalicylic acid (ASA) is widely used for its antiplatelet effects [1]. Low-dose aspirin (75 mg to 100 mg) is generally indicated in cases of angina, ischemic heart disease, post-myocardial infarction, post-bypass surgery, post-angiography/angioplasty, stroke, and transient ischemic attacks.[2]. But the fear of uncontrolled bleeding prompts physicians to stop aspirin intake before surgical procedures, including oral surgery.[3]; [25].

This puts the patients at risk of developing thromboembolism, myocardial infarction, or cardiovascular accident. [13].

GELFOAM Sterile Sponge is a water-insoluble, hemostatic device prepared from purified porcine skin gelatin, and capable of absorbing up to 45 times its weight of whole blood. [7].

The absorptive capacity of GELFOAM is a function of its physical size, increasing as the size of the gelatin sponge increases, the mechanism of action of surface-mediated hemostatic devices is supportive and mechanical. [10].

Surface-acting devices, when applied directly to bleeding surfaces, arrest bleeding by the formation of an artificial clot and by producing a mechanical matrix that facilitates clotting. [11].

[14]. have theorized that the clotting effect of GELFOAM may be due to release of thromboplastin from platelets, occurring when platelets entering the sponge become damaged by contact with the walls of its myriad of interstices.

Thromboplastin interacts with prothrombin and calcium to produce thrombin, and this

sequence of events initiates the clotting reaction. The authors suggest that the physiologic

formation of thrombin in the sponge is sufficient to produce formation of a clot, by its

action on the fibrinogen in blood.

The spongy physical properties of the gelatin sponge hasten clot formation and provide structural support for the forming clot.[11]; [14].

Several investigators have reported that GELFOAM becomes liquefied within a week or less and is completely absorbed in four to six weeks, without inducing excessive scar formation.[3,23,26]

Patients, Methods and Materials

We conducted a study of (60) Iraqi patients on long-term low-dose aspirin therapy scheduled for oral surgery. We did not stop aspirin for a single patient and did not face any untoward sequelae. We present our results and observations and propose that most minor oral surgical procedures can

be carried out safely without stopping low-dose aspirin therapy.

Their preoperative blood values of bleeding time and platelet counts were taken. They were found to be within normal limits in all cases. The oral surgical procedures were performed on an outpatient basis under local anesthesia. The procedures also included complex procedures, such as third molar surgery. A simple pressure pack and sutures were sufficient in all but 2 cases to secure hemostasis. Only 2 cases required intraoperative use of local hemostatic agent. Sufficient follow-up was completed and no untoward postoperative bleeding complications were encountered in any case.

This prospective study included (60) patients with the following criteria:

- 1 -Patients on long-term low-dose aspirin regimens (75 to 100 mg)
- 2 -Patient requiring minor oral surgery procedures that could be performed on an outpatient basis
- 3 -Patients who were not on any concurrent therapy such as birth control pills, hormone replacement therapy, other anticoagulation; or any drug such as NSAIDs that could interact with the aspirin
- 4 -Patients who presented to our hospital between September 2010 and April 2011
- 5 -Patients who gave written informed consent to be included in the study.

We performed a preoperative investigation of the bleeding time and platelet count of each patient. If these were within normal limits, we performed the surgery without stopping aspirin therapy.

If the values were abnormal, we would stop the low-dose aspirin for at least 7 days (with a consultation with patients' physicians) before operating, repeat the investigations, and then proceed.

All surgery was performed on an outpatient basis under local anesthesia (LIDOCAINE HYDROCHLORIDE 36.00000 mg/ ADRENALINE TARTRATE 0.04086 mg/ as Adrenaline 0.02250mg of 1.8 ml cartridge MERIGNAC – FRANCE).

Local haemostatic agents (Gel foam of 20mm x 60 mm sponges) as well as a surgical diathermy machine were kept in readiness to control any excessive bleeding encountered.

The intraoperative blood loss was measured by weighing the swabs and by subtracting the volume of irrigation fluid from the total volume of fluid in the suction jar. Less than 30 mL blood loss was considered not excessive and more than 30 mL was considered excessive. All surgical sites were sutured with 3/0 black braided silk and a pressure pack was given.

The patients were checked 30 minutes after the completion of the procedure and were then discharged with strict instructions. Postoperative medications such as antibiotics and analgesics were prescribed, if required.

Care was taken to prescribe paracetamol-based analgesics to avoid any interaction with aspirin. Follow-up was completed after 24, 48, and 72 hours, and at 1 week (when the sutures were removed) and 2 weeks.

Results

This prospective study was undertaken clinically on (60) patients presenting with minor oral surgery.

The ages of the patients ranged from 45 years to 75 years. (Table 1-1).

There were 35(58.33%) males and 25(41.7%) females. (Table 2-1).

The mean age ($\pm$ standard deviation) of patients in our study was 56.33 years $\pm$ 5.65.

The indications for aspirin therapy ranged from angina to post-bypass surgery.

All patients included in our study had been taking low-dose aspirin for a period ranging from 1 to 15 years. The mean ($\pm$ standard deviation) duration of aspirin therapy was 3.56 ± 3.41 years.

All patients had preoperative values within normal limits. The mean bleeding time ($\pm$ standard deviation) was $2.66 \text{ minutes} \pm 0.57$ and mean platelet count ($\pm$ standard deviation) was $286 \pm 48.53 \times 10^3/\text{mm}^3$.

Excessive intraoperative bleeding was encountered in (2) cases. (3.33%) (Table 3-1).

There was constant ooze during (1 lower third molar removal & 1 lower 2nd molar removal).

Put 2-3 sponges of gel foam and applying pressure for 10 minutes controlled the ooze.

A simple pressure pack and suturing was sufficient for securing hemostasis in all other cases. There was no postoperative bleeding in any case.

Discussion

[1] confirmed the prophylactic effects of aspirin after a previous myocardial infarction, in angina, after stroke, and after bypass surgery, and established its efficacy in women as well as men, in a meta-analysis of 140,000 patients in over 300 studies.

Vascular events are reduced by 20% to 25% in the first few years after the index event, and all-cause mortality is reduced by 12%.

Low-dose regimens retain efficacy yet limit gastrointestinal side effects. [30].

This has made low-dose aspirin regimens popular in the last decade. [9].

Aspirin causes inhibition of cyclooxygenase, which results in interference in the synthesis of

prothrombotic TXA_2 , which is important in the platelet activation cycle. Platelet dysfunction results and platelet aggregation in the blood is prevented. Platelet adhesion, activation, and aggregation is an important step in the formation of a thrombus, thus explaining in a simplified way the antithrombotic effect of aspirin. [30].

[29] established the role of platelets in hemostasis.

Platelet adhesion, activation, and aggregation are useful in the primary arrest of bleeding. [29].

As a result, there is risk of prolonged bleeding following surgery. Because of this risk, patients receiving long-term aspirin therapy are asked to discontinue use for 7 to 10 days before surgery. [5][24][25]

But interruption of the aspirin therapy may expose these patients to the risk of developing thromboembolism, myocardial infarction, or cerebrovascular accident. [13].

So there should be a consultation with patients' physicians, whether to stop or not stop the dose of aspirin before the minor surgery.

A search of the literature showed that most of the authorities were in favor of stopping aspirin therapy. [5][17][24][25][28].

However, [9] maintained that aspirin need not be stopped before any surgery. [19] recommend the continuation of aspirin therapy before elective dermatologic surgery if the bleeding time is within normal limits.

[2] argued in their study that long-term low-dose therapy should not be stopped before minor oral surgical procedures.

Investigation of the bleeding time and platelet count was performed preoperatively in all patients. The bleeding time and platelet count are the first-line basic laboratory tests of platelet

function used to investigate a bleeding diathesis. [4].

If these are normal, it is unlikely that a significant platelet defect is responsible for excessive clinical bleeding. [4].

According to our protocol, if the values were found to be abnormal, we would stop aspirin for 7 days as recommended by most experts (with patients' physicians' consultations), repeat the investigations, and then perform the surgery.

All the patients in our study had these values within normal limits, as seen in the Results and Observations section, so we went ahead and performed the surgery without stopping aspirin.

The minor surgical procedures were varied and many cases required mucoperiosteal reflection and bone cutting. We encountered excessive intraoperative bleeding in only 2 cases (lower 3rd molar surgery & lower 2nd molar surgery). However, we believe it may have been caused by mild injury to the inferior alveolar neurovascular bundle.

It was controlled by putting 2-3 sponges of gel foam (20mm x 60 mm) and applying pressure for 10 minutes. There was no postoperative bleeding in any case.

Surface-acting devices, when applied directly to bleeding surfaces, arrest bleeding by the formation of an artificial clot and by producing a mechanical matrix that facilitates clotting [11].

[14] have theorized that the clotting effect of GELFOAM may be due to release of thromboplastin from platelets, occurring when platelets entering the sponge become damaged by contact with the walls of its myriad of interstices.

The spongy physical properties of the gelatin sponge hasten clot formation and provide structural support for the forming clot. [11][14].

Several investigators have reported that GELFOAM becomes liquefied within a week or

less and is completely absorbed in four to six weeks, without inducing excessive scar

formation.[3][7][14][23][26]

Conclusion

Through this clinical prospective study we are able to conclude that most minor oral surgical procedures can be safely carried out without stopping long-term low-dose aspirin therapy.

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Table 1-1 Demography or age range of the patients

Age range	Frequency	Percentage
45	6	10%
46-55	19	31.7%
56-65	20	33.3
66-75	15	25%
Total	60	100%

Table 2-1 Gender or sex distribution of the patients

Gender	Number of cases	Percentage
Male	35	58.33%
Female	25	41.7%
Total	60	100%

Table 3-1 Bleeding distribution

Intra-operative bleeding	Number of cases	percentage
Bleeding	2	3.3%
No bleeding	58	96.7%
Total	60	100%